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**2002 ED**

# **NVCASE Program Handbook**

## **Procedures for Obtaining NIST Recognition as an Accreditor**

R. L. Gladhill  
Jogindar Dhillon

**NIST**

**National Institute of Standards and Technology**  
Technology Administration, U.S. Department of Commerce

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R. L. Gladhill  
Jogindar Dhillon  
*Standards Services Division  
Technology Services  
National Institute of Standards and Technology  
Gaithersburg, MD 20899-2100*

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U.S. Department of Commerce  
*Donald L. Evans, Secretary*

Technology Administration  
*Phillip J. Bond, Under Secretary for Technology*

National Institute of Standards and Technology  
*Arden L. Bement, Jr., Director*



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## 1.0 INTRODUCTION

This handbook provides guidance to bodies desiring to obtain recognition as an Accreditation Body (accreditor) under the National Voluntary Conformity Assessment Systems Evaluation Program (NVCASE). It explains the generic procedures, conditions, and requirements for NIST recognition. NIST established NVCASE in 1994. Its operating rules are found at 15 CFR Part 286.

The NVCASE program supports NIST obligations as a Designating Authority for Conformity Assessment Bodies (CABs) as specified in inter-governmental Mutual Recognition Agreements (Arrangements) (MRAs) with other nations (e.g., the U.S./European Union (EU) MRA, the Asia Pacific Economic Cooperation (APEC) MRA, Inter-American Telecommunications Commission (CITEL) MRA). It also supports requests from other Government regulatory agencies when CAB evaluation is required, (e.g., the Federal Communications Commission (FCC) Telecommunications Certification Body (TCB) Program, FCC Docket 98-68.)

An accreditor that obtains NIST recognition through the NVCASE evaluation process can then nominate bodies (to NIST) that it has accredited that fulfill the necessary requirements to be formally forwarded by NIST to the other agency or MRA partner(s). Qualified conformity assessment bodies may then test and/or certify products either to satisfy mandatory foreign requirements or to support domestic regulatory programs.

The generic requirements described in this handbook are based upon ISO/IEC documents Guides 58 and 61. Annexes A, B, and C provide detailed criteria for the type of accreditation offered by an applicant, namely, laboratory accreditation, quality system registrar accreditation and product certifier accreditation respectively. Technical requirements for the scope of accreditation under a particular MRA agreement or regulatory program are contained in supplements to the annexes.

NIST invites readers/users to offer comments, suggestions for clarification or improvement, or other constructive feedback regarding the NVCASE program or this document.

### 1.1 Definitions

For purposes of this handbook the following definitions are used.

- 1.1.1 Authorized Representative:** An employee of an accreditor with the authority to make binding commitments on behalf of the organization. The authorized representative is the person who will be responsible for all communications with NIST and who will ensure that the accreditor complies with all NIST/NVCASE program requirements.



- 1.1.2 **Evaluation** The overall process of review and appraisal, by NVCASE or an accreditor, to determine if an entity (an accreditor, a laboratory, a certifier, or a registrar) satisfies all applicable requirements, e.g., quality system review, results of on-site assessment, applicant proposals to correct non-conformities, etc.
- 1.1.3 **Assessment/Audit** The on-site review of an accreditor by NVCASE or the on-site review of a client of an accreditor (laboratory, certifier, or registrar) by the accreditor (The term assessment is normally used in conjunction with review of laboratories, and product certifiers, and audit is normally used in conjunction with review of quality systems.)
- 1.1.4 **Witness Audit** The observation by NVCASE staff and/or technical assessors of an applicant accreditor's assessor(s)/auditor(s) performing an assessment/audit of a client's facilities.

## 2.0 REQUESTING EVALUATION

### 2.1 Who May Apply

Any domestic accreditor, government or private, that wishes to be recognized may submit an application for evaluation to NIST. The application must be completed and signed by the Authorized Representative of the accreditor.

### 2.2 Application Package

Application packages may be requested from NVCASE Program Manager, NIST, 100 Bureau Drive, Stop 2100 Gaithersburg, Maryland, 20899-2100. Packages include: the **General Application**, the **Program Handbook**, **Annexes**, the **Fee Schedule**, and other documents needed for understanding of the program and requirements. Requests may be made by mail, or by Fax to: (301) 963-2871.

All application forms must be completed in English with sufficient information and detail to fully describe the accreditation organization. The applicant may submit any applicable enclosures or attachments appropriate to describe capabilities or resources.

An application may be amended at any time prior to a final decision. However, dependent upon the nature of changes, delay and additional cost for NIST to evaluate such changes may be incurred by the applicant. An application may be withdrawn at any time prior to a final decision. If an application is withdrawn, the entity may later reapply. (See section 3.5 for NIST's refund policy).



## **2.3 NIST Acknowledgment**

NVCASE will acknowledge receipt of each application, confirm payment of the application fee, and specify to the applicant the next step(s) in the evaluation process. If necessary, further information may be requested. If an applicant is deemed to be ineligible, all submitted information and fees will be returned with an explanation of the ineligibility.

## **3.0 FEES**

NVCASE operates on a cost-reimbursable basis; fees are charged to users for services rendered.

### **3.1 Application Fee**

The application fee is an estimate by NVCASE of the cost to perform an evaluation and must be submitted with the application. Once the evaluation has been completed, the applicant will either be billed for, or refunded, the difference between the amount submitted and the actual costs incurred by NVCASE.

### **3.2 Periodic Reassessment Fee**

Each recognized accreditor will undergo a reassessment visit every two years. A reassessment fee is required.

### **3.3 Additional Costs**

From time to time, additional NVCASE evaluation activities may be necessary. Since these activities are not predictable, e.g., special assessments resulting from citation of major deficiencies, investigation of complaints received, changes in management or location of a participant, etc., attendant costs will be billed to participants as appropriate.

### **3.4 Fee Schedule**

The NVCASE Program Fee Schedule is available from NIST; applicable fees may be changed by NIST when necessary. A new schedule will be provided to participants if and when fees are changed.

### **3.5 Refund Policy**

If an applicant is deemed to be ineligible or withdraws the application prior to any action by NVCASE described in section 4, the application fee will be fully refundable. Once NVCASE has begun an evaluation and has incurred costs, NIST will refund the application fee minus these incurred costs. Refunds must be requested from the NVCASE Program Manager.

### **3.6 Payment of Fees**

An applicant must have paid all amounts due before recognition can be granted. An applicant must also pay all fees due for all incurred costs even if recognition is not granted.

## **4.0 NVCASE EVALUATION PROCESS**

The process of evaluating an applicant consists of a number of activities, which must take place prior to and after granting recognition. The process begins with an initial review of the application followed by review of the applicant's quality system, on-site assessment/reassessment of the premises, witness audits of assessments performed by the applicant's assessors, writing an assessment report, review of applicant response to the assessment report, and final evaluation and decision. Surveillance activities and on-site reassessment visits of recognized accreditors are conducted periodically.

### **4.1 Assessment Team**

An assessment team comprised of one or more NVCASE staff members and one or more appropriate technical experts conducts the assessment. In some instances selected observers may also be involved, e.g., representatives of appropriate regulatory agencies, special technical consultants, persons participating in cooperative assessments.

### **4.2 Ethics - Confidentiality**

All persons involved in the evaluation process, including NIST staff, the assessment team, review panel, observers, etc. treat as confidential all information and conversations pertaining to any part of the evaluation in which they are involved. Information is disclosed only as may be required by law. All persons involved in the evaluation process are required to sign an ethics statement and adhere to a strict code of conduct.

If anyone is required to review information considered proprietary, all such information is treated accordingly. Refusal to allow review of such materials that are applicable to the desired recognition may result in denial of recognition.

### **4.3 Quality System Review and Evaluation**

Each applicant must submit copies of its quality documentation for review and evaluation. The documentation must show that the quality system promotes an adequate level of performance and quality management. NIST may interact with the applicant to obtain clarification of certain items or to request additional information.

If an applicant cannot submit documentation in advance, the quality system review can be performed during the on-site assessment, but additional expense to the applicant may be incurred if extra time is required.

#### **4.4 On-site Assessment**

An on-site assessment of an applicant's facilities is conducted prior to initial recognition and every second year thereafter unless the recognition is terminated. The assessment encompasses an on-site review of selected procedures and operations for all sites involved in the accreditation activities that the recognition would cover.

NVCASE will contact the applicant to arrange a mutually convenient date for the visit, develop an agenda, and inform the applicant of the identity of the assessment team. The applicant may appeal the inclusion of any member of the team. Such appeal must be received in writing at least 20 working days prior to the scheduled date of the visit and must provide a substantive reason in order for a change to be made.

If the personnel of the applicant being evaluated normally speak (or any documentation needing review is written in) a language other than English, either NVCASE or the applicant may arrange for an interpreter to accompany the assessment team. Any cost incurred by NVCASE will be charged to the applicant.

The normal sequence of a NVCASE on-site assessment is:

*4.4.1 Entrance Meeting:* Upon arrival at the applicant's premises, the assessment team meets with management to discuss what is to be accomplished and agree on a plan of action. The meeting allows all parties to become acquainted and gives the assessment team the opportunity to understand the management structure. It is recommended that a staff member be designated as the main contact person to assist the assessment team.

*4.4.2 Walk Through and Staff Introductions:* The assessment team briefly tours the premises to familiarize themselves with the layout and to get acquainted with staff members who are responsible for the areas of interest.

*4.4.3 Assessment:* The assessment focuses on ascertaining that the actual operation of the accreditor is the same as described in the quality documentation. All procedures involved in the accreditation process are reviewed. All phases of the operation pertaining to the scope of the request for evaluation are subject to review. A checklist developed from the criteria contained in Section 7 of this Handbook is used to guide the review and ensure uniformity of assessment from one applicant to another.

The assessors review relevant documents and files, observe specific operations, and interview staff members for such things as information and reporting systems, database



systems; files, records, documents relating to accreditation procedures, policies, and activities; assessment reports of selected clients, final evaluation reports on which accreditation was based; appeals and complaints regarding the accreditor, and auditor qualification, training, and competency records.

Personnel representing the following must be available for interview:

- management personnel;
- clerical and support personnel;
- technical project managers;
- quality assurance staff,
- auditors/assessors, and persons who make accreditation decisions; (*need not be on-site but must be able to be contacted for interview*)

**4.4.4 Development of Draft Assessment Report:** The assessment team develops a draft report containing a comprehensive review of its findings. The report will contain elements of both the on-site visit of the applicant and any witness audits. Any deficiencies requiring resolution are clearly identified.

**4.4.5 Exit Meeting:** Once the assessment team is satisfied that it has completed its task at the site and has developed a draft report, a meeting is held with management to discuss the findings. At the conclusion of this meeting the Authorized Representative of the Accreditor must sign the draft report, acknowledging the discussions and the responsibility to respond, in the allotted time, to any identified deficiencies.

#### **4.5 Witness Audits/Assessments**

As part of the evaluation process, an applicant must allow members of the NVCASE assessment team to witness the applicant's auditors/assessors performing an assessment/audit of a client's facilities. NVCASE will discuss with the applicant the number and identity of the witness audits to be performed. The applicant must pay all applicable costs incurred by NVCASE in conducting witness audits.

#### **4.6 Final Report**

NVCASE staff prepares a final report and forwards it to the applicant, after the assessment. The final report usually will be essentially the same as the draft report unless additional information has been uncovered, or issues that require clarification have arisen.

The final report normally presents the definitive findings of the assessment. However, if additional information surfaces with significant bearing on the evaluation, a supplementary report may be necessary. Any supplementary report that requires action will be promptly forwarded to the applicant.

#### **4.7 Applicant Response to Assessment Report/Deficiency Notification**

The applicant must respond in writing to NVCASE to all identified deficiencies. All specific corrective actions taken, and proposed plans to resolve each deficiency, must be described in writing. Plans must include specific actions, time frames, dates, etc. In some cases, an additional on-site visit, at additional cost, may be necessary to observe stated resolutions.

New applicants are generally expected to resolve deficiencies within 90 days or as mutually agreed for a shorter time period; **NVCASE must be informed if additional time is required.** If the applicant's actions cause the evaluation process to take longer than one year, additional administrative costs may be incurred.

Accreditors holding a current valid NIST recognition must resolve all deficiencies cited within 30 days of receipt of a deficiency notification or recognition may be suspended until full conformance is demonstrated.

#### **4.8 Final Evaluation Decision**

Upon completion of all evaluation activities, NIST will convene an evaluation panel to review all information collected regarding an applicant and make a final decision on the appropriate recognition action to take. (See 5.0 Program Actions)

The decision is based on the review and evaluation of all materials submitted by the applicant, reports covering the quality system review, on-site assessment(s) report, witness audit reports, and deficiency resolution information.

The panel is comprised of NIST staff, selected technical experts, and representatives of cognizant regulatory agencies and representatives of joint evaluation bodies, as appropriate.

The panel would consist of a minimum of three voting members with at least one from the regulatory agency. The NIST assessor will present the results of the on-site evaluation, witness audit(s) reports, deficiency reports and their resolutions by the candidate accreditor, and a recommendation for a decision. Then, a question/answer and discussion session will follow. At the end of the discussion period, the NIST assessor will ask for a vote on his/her recommendation. Consensus is always the desired goal. However, 100% agreement may not be always possible. If a formal vote is necessary, a minimum of 2/3-majority of the voting panel members is required for recognition of the candidate accreditation body. The cognizant regulatory agency's panel member vote must be among the positive 2/3-majority vote.

#### **4.9 Surveillance**

NVCASE may, at its discretion, whether or not for cause, conduct a full or partial on-site visit or other forms of surveillance of a recognized accreditor or any accredited body to observe or verify

conformance with program requirements. Any deficiencies noted as a result of surveillance must be responded to in accordance with Para. 4.7.

## **5.0 PROGRAM ACTIONS**

NVCASE may grant, deny, suspend, or terminate recognition of an accreditor.

### **5.1 Granting Recognition**

An applicant who demonstrates conformance with all Program requirements will be granted recognition as having demonstrated the ability to evaluate and accredit bodies and publicly attest to their conformance with NVCASE requirements.

The applicant is provided with documentation stating the terms and conditions of the recognition and the specific Scope of Activities for which recognition is granted.

### **5.2 Denial**

Recognition will be denied if an applicant fails to demonstrate conformance with the NVCASE Program requirements. NIST will notify the applicant in writing of its intention to deny and the reason(s) therefor. An applicant is given 90 days to resolve any deficiencies which form the basis of the proposed denial. Unless resolution is achieved in that time, the applicant is denied recognition.

An applicant may appeal a denial by submitting a statement of reasons why recognition should not be denied to the NIST Deputy Director (See 5.6 Appeal.)

### **5.3 Suspension**

If it is determined that a recognized accreditor temporarily cannot demonstrate conformance, e.g., a serious deficiency is uncovered during surveillance or the accreditor has changed ownership or location, or other substantive reason emerges, NIST may suspend recognition until full conformance has again been demonstrated.

If recognition is suspended by NIST, the accreditor may neither grant any additional accreditations, nor conduct any other evaluation activities covered by the recognition after the date of the suspension. The accreditor must, within 5 days of receipt of notification of suspension, inform, in writing, all bodies that it has accredited under the terms of the NIST recognition that its NIST recognition has been suspended.

The accreditor's written notice shall state the effective date of its suspension and shall also inform the accredited bodies that their current status with NIST will not change, unless they contributed to the conditions which led to the accreditor's suspension, or if, in NIST's judgement, a change is



otherwise justified.

## 5.4 Termination

Termination of participation in the NVCASE Program of a recognized accreditor may be voluntary or involuntary.

*5.4.1 Voluntary Termination:* A recognized accreditor may at any time voluntarily terminate its participation in the Program by giving written notice to NVCASE and to all bodies it has accredited.

*5.4.2 Involuntary Termination:* NIST may terminate, fully or partially, the recognition of an accreditor whenever it deems such action to be in the public interest. Such an action may result if the recognized accreditor engages in fraud or other illegal activity, is unable to meet NVCASE requirements, or exhibits other factors detrimental to producing an acceptable accreditation program.

*5.4.3 Termination Procedures:* NIST will notify the recognized accreditor in writing of the intent to terminate the recognition and the reason(s) therefor. The notice will state, as a minimum, that recognition is suspended as of the date of the notice, and that the accreditor may not grant any additional accreditations or conduct any evaluation activities covered by the recognition.

The recognized accreditor is given the opportunity to respond to or rebut stated reasons for termination or to correct any deficiencies which formed the basis of the proposed termination. If the basis for the termination is not reconciled within 30 days, or such longer time as NIST may allow, the termination becomes effective.

The recognized accreditor may appeal to the NIST Deputy Director by submitting a statement of reasons why the recognition should not be terminated. NIST may, at its discretion, delay implementing the termination action pending a final decision by the Deputy Director. If recognition is terminated, the accreditor may neither state nor imply that it has NIST recognition, nor may it grant any accreditation covered by the terminated recognition.

NVCASE may send a written notice to all bodies accredited by the terminated accreditor informing them of the termination and the effective date. The notice shall inform all affected bodies that their accredited status and NIST listing will not change unless they contributed to the conditions which led to the suspension of the accreditor, or in NIST's judgement removal from the NIST list is otherwise justified. They will be advised that, if they want to continue their NIST-listed status, they should expeditiously seek accreditation from another NIST recognized accreditor.

An accreditor whose recognition has been terminated may submit a request for re-evaluation when it believes that it can again demonstrate conformance with the NVCASE requirements.

### **5.5 Options in Response to an Adverse Action**

If NIST proposes to deny, suspend, or terminate recognition, and the applicant or recognized accreditor has been so notified in writing, citing the specific reasons or elements of nonconformance with the requirements, the accreditor may choose to:

- a) Appeal the decision and request that recognition be granted or continued by providing appropriate justification.
- b) Submit additional information for further evaluation. If additional on-site visits, etc., are required, additional costs may be incurred by the accreditor.
- c) Accept the decision.

### **5.6 Appeal**

An applicant or a recognized accreditor under the Program may appeal to the Deputy Director, NIST, any action taken against it. All appeals must be in writing and must include complete documentation setting forth the appellant's position. The appeal of an action must be filed with NIST within 30 days of that action.

Appeals should be addressed to: The Deputy Director, National Institute of Standards and Technology, Stop 1000, Gaithersburg, Maryland 20899-1000. The applicant or recognized accreditor will be informed of the Deputy Director's decision within 60 days following receipt of an appeal.

### **5.7 Scope Amendment (Extension or Reduction)**

A NIST-recognized accreditor under the NVCASE program may apply for scope amendment (extension or reduction). The types of scope extension/reduction available may relate to any of the following:

- (a) The requirements of a product certification program administered by a Federal agency (e.g., FCC's Telecommunication Certification Bodies Program)
- (b) Government-administered product certification requirements of an individual country signatory to a Mutual Recognition Agreement/Arrangement (MRA) that the United States Government has negotiated with that government (e.g., Industry Canada's product certification requirements under the Asia Pacific Economic Cooperation MRA for Telecommunications Equipment)
- (c) Product certification requirements of an industrial sector
- (d) Product categories (e.g., telecommunications equipment that includes fixed terminal equipment, radio, and transmitter equipment)

5.7.1 A NIST-recognized accreditor may request an extension of its current scope of recognition by providing the following documentation to NIST:

- (i) A cover letter requesting the type(s) of scope extension
- (ii) Copies of any additional documents or documents that have been revised as a result of scope extension. These documents may include the revised Policy/Quality Manual, Procedures, and Forms etc. Provide a list of revised sections in these documents. There is no need to submit documents that have not changed and were included in the prior assessment.
- (iii) The name(s) and qualifications of the assessor(s)/technical expert(s) who have the capability for the expanded scope.

NIST will provide an estimate for the scope extension fee in conformance with Section 3.0 of this Handbook. The accreditor must pay the estimated fees to NIST before the request for scope extension can be acted upon.

5.7.2 Procedures for scope extension

- (i) Upon receipt of a request for scope extension, NIST will review the request and the documentation.
- (ii) If an on-site visit is necessary, NIST will inform the accreditor and schedule an on-site evaluation for scope extension at a mutually agreeable date. The on-site evaluation may be combined with a regularly scheduled audit.
- (iii) NIST will participate in at least one witness audit conducted by the accreditor's assessors that involves an assessment to the expanded scope being sought by the accreditor.

5.7.3 Upon successful completion of evaluation activities, NIST will obtain a panel decision in accordance with Section 4.8 of this Handbook. This decision will be communicated to the accreditor. If the scope extension is denied, the accreditor may appeal in accordance with Section 5.5 of this Handbook.

5.7.4 Procedures for scope reduction: A NIST-recognized accreditor may request in writing a voluntary reduction in its currently recognized scope.

- (i) The accreditor shall make a request to NIST for a voluntary scope reduction in a letter listing all the current scopes, specifying the scope that is to be reduced.
- (ii) The request for a reduction in scope will be reviewed and approved by the Chief, Standards Services Division or a higher NIST official.



- (iii) Upon approval of a reduction in scope, the accreditor shall inform in writing all the Certification Bodies that are affected by its scope reduction.

5.7.5 NIST may involuntarily reduce the scope of an accreditor if NIST determines that the accreditor is unable to comply with the requirements of a particular type of scope.

- (i) The matter will be discussed with the accreditor before taking this action.
- (ii) If the accreditor is not agreeable to reduce the scope as discussed by NIST then a surveillance visit will be required. NIST shall conduct the surveillance in accordance with Section 4.9 of this Handbook. The accreditor must pay the fees for the surveillance visit as assessed by NIST.
- (iii) The procedures for an accreditor's appeal of an adverse action shall be in accordance with Section 5.5 of this Handbook.
- (i) Upon a reduction in scope by NIST, the accreditor shall inform in writing all the Certification Bodies that are affected by its scope reduction.

## **6.0 OBLIGATIONS OF A RECOGNIZED ACCREDITOR**

### **6.1 Continuous Conformance**

It shall be incumbent upon a recognized accreditor to conform to all requirements throughout the period of participation. Failure to maintain conformance is cause for suspension/termination of recognition.

Upon request, a recognized accreditor shall make available to NVCASE any document, information, or material related to the recognized accreditation activities.

### **6.2 Proper Use of Accredited Status and Claims**

A recognized accreditor shall not make any claim which:

- a) constitutes or implies certification, approval, or endorsement by NIST or any other agency of the U.S. government of any product manufactured or entered into commerce in the United States based on its recognition by NIST.
- b) constitutes or implies that the accreditor, or an accredited body is recognized by NIST or NVCASE for any activities other than those specifically stated in the NIST recognition documents.

A recognized accreditor must follow NVCASE guidance when advertising its accredited status on letterheads, brochures, reports, or in professional, technical, trade, or other publications. When the

acronym NVCASE or NIST is used it must be accompanied by the statement "Recognized by the National Institute of Standards and Technology for a specific scope of activities".

### **6.3 Keeping NVCASE Informed**

*6.3.1 Organizational Changes:* A recognized accreditor must inform NVCASE within 10 days of any major change in any factors which might affect its ability to operate, such as replacement of personnel (e.g., the Executive, key supervisors, and accreditation decision makers); any major change in procedure, policy making or direction; or change in location, ownership, or business affiliations. Failure to provide timely and accurate information may result in suspension or termination of recognition.

*6.3.2 Accredited Body Status:* NIST will maintain a list of all bodies that have been accredited by all accreditors recognized by NIST. The list will be made available through various media including the Internet.

Each recognized accreditor must keep NVCASE informed of all accreditation actions under the NIST recognition. This information is vital for maintaining up-to-date lists. All applicable new accreditations, renewals, terminations, revocations, suspensions, changes in scope (additions or deletions) must be reported to NVCASE within seven days, in English, by the recognized accreditor.

When required, the recognized accreditor's notification of accreditation status to NVCASE must include the following elements of information:

1. Name of recognized accreditor
2. Name of accredited body
3. Address of body (country, state, city, and postal code)
4. Copy of accreditation certificate
5. Name of Authorized Representative and telephone/Fax /E-mail numbers
6. Nature of the accreditation action (e.g., initial, renewal, change in scope, etc.)
7. Scope of accreditation/change and effective dates

*6.3.3 Recognized Accreditors List:* NIST will maintain a list of the names and pertinent information for all recognized accreditors. A recognized accreditor must remain in conformance with all NVCASE conditions and requirements to retain its listing. The list will be made available through various media including the Internet.

## **7.0 ACCREDITOR REQUIREMENTS**

Accreditors must comply with the appropriate generic standard e.g., ISO/IEC Guide 58 or 61 and

supplementary specific sectoral requirements. The annexes noted below contain the requirements for each specific type of accreditation body. Each annex has supplements with additional criteria for the specific sector, MRA or regulatory program.

Annex A - Laboratory Accreditation Bodies

Annex B - Product Certification Accreditation Bodies

Annex C - Quality System Registrar Accreditation Bodies

## **8.0     SECTORAL SUPPLEMENTS**

Many NVCASE sub-programs support the operation of inter-governmental MRAs between the United States and other governments. Since requirements normally differ among MRA's and product sectors, the specific requirements for a given sub-program are detailed in supplements to the general requirements.

Specific technical requirements are normally dictated by the other MRA partner(s') regulatory requirements, by the specific agreement, by a domestic regulatory requirement, or by the industry sectors involved. Some supplements are included in this document; others will be added as they are developed. Since the NVCASE development process for new programs is on-going based on requests from the private sector, other government agencies, or newly negotiated MRAs, new supplements are being continually developed. Please contact NVCASE if relevant supplement(s) is/are not included.



## **ANNEX A - Requirements for accreditors of testing laboratories**

### **1.0 INTRODUCTION**

This annex sets out generic organizational, operational and other requirements that must be met in order for an accreditor of testing laboratories to be recognized by NIST. It also sets out the requirements against which an accreditor shall assess the competence of a testing laboratory desiring accreditation.

### **2.0 ACCREDITOR REQUIREMENTS**

#### **2.1 General**

The basic generic criteria that an accreditor must satisfy are contained in *ISO/IEC Guide 58 - Calibration and Testing Laboratory Accreditation Systems - General requirements for Operation and Recognition*

#### **2.2 Specific NIST requirements**

##### **2.2.1 Organization**

**The senior executive** shall have sufficient experience and demonstrated ability in the successful operation of an accreditation program operating on a national or international scale. The executive shall have appropriate experience/education in management principles/application, technical knowledge, and personnel management.

**The Accreditor** shall have access to appropriate experts, professional services or resources that can be used for technical support, advice and assistance in the specific technical area(s) that it will perform accreditation under the NIST recognition.

##### **2.2.2 Subcontracting**

The accreditor must inform NIST, before the fact, whenever subcontracting will be necessary; and clearly indicate in all appropriate records and reports to the client specifically what functions were subcontracted.

### **3.0 ACCREDITATION CRITERIA FOR LABORATORIES**

#### **3.1 General Requirements**

An accreditor shall accredit applicant laboratories against ISO/IEC Guide 25 - *General Requirements for the Competence of Calibration and Testing Laboratories*.

#### **3.2 Specific Requirements**

Requirements for specific applications are contained in attached supplements. See the particular supplement(s) of interest.

#### **4.0 Reference to NVCASE**

A NIST recognized accreditor may not refer to the acronym NVCASE in any reports issued, advertisements, or other document issued by the accreditor except to state that they have been recognized by NIST-NVCASE to offer accreditation for a specific scope of recognition.

An accredited laboratory may not refer to the acronym NVCASE in any reports issued, advertisements, or other document issued by the laboratory except to state that they have been accredited by a NIST recognized accreditor and that accreditor is specifically named in the statement.

## **ANNEX B- Requirements for accreditors of product certification systems**

### **1.0 INTRODUCTION**

This annex sets out generic organizational, operational and other requirements that must be met in order for an accreditor of product certification systems to be recognized by NIST. It also sets out the requirements against which an accreditor shall assess the competence of a product certifier desiring accreditation.

### **2.0 ACCREDITOR REQUIREMENTS**

#### **2.1 General**

The basic general criteria that an accreditor must satisfy are contained in ISO/IEC Guide 61- *General requirements for Assessment and Accreditation of Certification/Registration Bodies*

#### **2.2 Specific NIST requirements**

##### **2.2.1 Organization**

**The senior executive** shall have sufficient experience and demonstrated ability in the successful operation of an accreditation program operating on a national or international scale. The executive shall have appropriate experience/education in management principles/application, technical knowledge, and personnel management.

**The Accreditor** shall have access to appropriate experts, professional services or resources that can be used for technical support, advice and assistance in the specific technical areas that it will perform accreditation under the NIST recognition.

##### **2.2.2 Subcontracting**

The accreditor must inform NIST, before the fact, whenever subcontracting of any accreditation functions are necessary; and clearly indicate in all appropriate records and reports specifically what functions were subcontracted.

### **3.0 ACCREDITATION CRITERIA FOR CERTIFIERS**

#### **3.1 General Requirements**

An accreditor shall accredit applicant product certification systems to ISO/IEC Guide 65 - *General Requirements for Bodies Operating Product Certification Systems*. .

#### **3.2 Specific Requirements**

Requirements for specific applications are contained in attached supplements. See the particular supplement(s) of interest.

### **4.0 Reference to NVCASE**

A NIST recognized accreditor may not refer to the acronym NVCASE in any reports issued, advertisements, or other document issued by the accreditor except to state that they have been recognized by NIST-NVCASE to offer accreditation for a specific scope of recognition.

An accredited product certifier may not refer to the acronym NVCASE in any reports issued, advertisements, or other document issued by the certifier except to state that they have been accredited by a NIST recognized accreditor and that accreditor is specifically named in the statement.

## **ANNEX C - Requirements for accreditors of quality system registrars**

### **1.0 INTRODUCTION**

This annex sets out generic organizational, operational and other requirements that must be met in order for an Accreditor of Quality System Registrars to be recognized by NIST. It also sets out the requirements against which an accreditor shall assess the competence of a quality system registrar desiring accreditation and the requirements for a registrar to register an organization as satisfying specified quality system requirements.

### **2.0 ACCREDITOR REQUIREMENTS**

#### **2.1 General**

The basic generic criteria that an accreditor must satisfy are contained in ISO/IEC Guide 61 - *General requirements for assessment and accreditation of certification/registration bodies*.

#### **2.2 Specific NIST requirements**

##### **2.2.1 Organization**

**The senior executive** shall have sufficient experience and demonstrated ability in the successful operation of an accreditation program operating on a national or international scale. The executive shall have appropriate experience/education in management principles/application, technical knowledge, and personnel management.

**The Accreditor** shall have access to appropriate experts, professional services or resources that can be used for technical support, advice and assistance in the specific technical area that it will perform accreditation under the NIST recognition.

##### **2.2.2 Subcontracting**

The accreditor must inform NIST, before the fact, whenever subcontracting will be necessary; and clearly indicate in all appropriate records and reports to the client specifically what functions were subcontracted.



### **3.0 ACCREDITATION CRITERIA FOR REGISTRARS**

#### **3.1 General Requirements**

An accreditor shall accredit applicant registrars against ISO/IEC Guide 62 - *General Requirements for Bodies operating assessment and certification/Registration of Quality Systems*.

#### **3.2 Specific Requirements**

Requirements for specific applications are contained in attached supplements. See the particular supplement(s) of interest.

### **4.0 REQUIREMENTS FOR REGISTERED ORGANIZATIONS**

A registrar shall audit bodies desiring registration against the appropriate quality standard(s) required by the particular MRA partner, regulatory requirement or other document specified in the applicable supplement to this annex.

### **5.0 REFERENCE TO NVCASE**

A NIST recognized accreditor may not refer to the acronym NVCASE in any reports issued, advertisements, or other document issued by the accreditor except to state that they have been recognized by NIST to offer accreditation for a specific scope of recognition.

Neither an accredited registrar, nor a registered organization, may refer to the acronym NVCASE in any reports issued, advertisements, or other document issued by the registrar, or organization, except to state that they have been accredited/registered by a NIST recognized accreditor and that accreditor is specifically named in the statement.





